

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

In re: Zytiga Litigation

Master Docket No. 19-12107 (KM)(ESK)

This Document Relates To: *Qui Tam* Action
and End-Payor Class Action

**STIPULATION AND ORDER CONCERNING PROTOCOL FOR
DISCOVERY OF ELECTRONICALLY STORED INFORMATION
AND HARDCOPY DOCUMENTS**

WHEREAS, in accordance with Federal Rule of Civil Procedure 26(f) and Local Rule 26.1(d), counsel have met and conferred regarding application of the discovery process set forth in the Federal Rules of Civil Procedure and the Local Civil Rules to this case;

WHEREAS, the Parties have reached agreement on certain of the issues discussed regarding such discovery;

WHEREAS, the Parties have entered into this Stipulation and Order Concerning Protocol for Discovery of Electronically Stored Information and Hardcopy Documents (“Stipulation and Order”) to facilitate the conduct of discovery involving electronically stored information (“ESI”) and to promote, to the fullest extent possible, the resolution of disputes regarding the discovery of ESI without Court intervention;

IT IS HEREBY ORDERED that:

1. Scope.

a. Subject to the Protective Order entered in these actions, this Stipulation and Order shall govern the discovery of documents and ESI, as described in Fed. R. Civ. P. 26, 33, and 34;

b. All Parties are bound by and subject to the terms of this Stipulation and Order.

2. Cooperation. The Parties agree to cooperate in seeking to efficiently conduct discovery in this matter.

3. No Designation of Discovery Requests. Productions of materials in the reasonably usable form set out in this protocol, including Attachment A, need not be organized and labeled to correspond to the categories in the requests. However, a producing party should provide information concerning the source of the documents being produced (*i.e.*, “this production consists of documents from the custodial files of Person A, Person B, and Person C.”).

4. Search Methodology.

a. The Parties expect to employ one or more search methodologies, including possibly but without limitation the use of advanced search and retrieval technologies, to identify potentially relevant ESI, including email. The parties agree to further meet-and-confer on this subject prior to the commencement of discovery beyond that called for in the Court’s Order of July 8, 2021.

b. The fact that any electronic file has been identified in agreed-upon searches shall not prevent any Party from withholding such file, or some portion of it, from production on the grounds that the file, or some portion of it, is protected from disclosure by applicable privilege or immunity, or is otherwise allowed to be withheld pursuant to the Parties’ agreement or an Order entered by this Court. In each case, any responsive portion(s) not subject to privilege, privacy law or regulation, or the Protective Order shall be produced.

c. Nothing in this section shall limit a Party's right reasonably to seek agreement from the other Parties or a court ruling to modify previously agreed-upon search terms or procedures for advanced search and retrieval technologies.

5. Prioritized Searching.

a. Data Sources that are Reasonably Accessible. Any search for potentially relevant documents or ESI shall involve searching for such documents in data sources within which such documents and ESI are likely to be most readily accessible.

6. Deduplication.

a. A Party is only required to produce a single copy of a responsive document. Parties may deduplicate stand-alone documents or entire document families vertically within each custodian or horizontally (also referred to as globally) across custodians, as to exact duplicates. Documents are exact duplicates if they have matching MD5 or SHA-1 hash values. When duplicate ESI exists in the files of multiple agreed-on custodians and a party deduplicates its production, the names of those custodians shall be listed in the OTHER_CUSTODIANS field identified in Paragraph A.13(c) of Attachment A.

b. When comparing document families, if a parent document is an exact duplicate but one or more attachments or embedded files are not exact duplicates, neither the attachments or embedded files nor the parent document will be deduplicated.

c. Attachments to emails shall not be eliminated from their parent emails. Where a stand-alone document is an exact duplicate of an email attachment, the email attachment must be produced and the stand-alone document may be deduplicated.

d. If the Producing Party makes supplemental productions following an initial production, the Party shall also provide with each supplemental production an overlay filed to allow the Receiving Party to update the OTHER_CUSTODIANS field.

7. Known Software Files. Known software files (*i.e.*, applications) identified in the National Software Reference Library database maintained by the National Institute of Standards and Technology need not be collected or produced.

8. Email Threads.

a. The parties agree to further meet-and-confer on this subject prior to the commencement of discovery beyond that called for in the Court's Order of July 8, 2021.

9. Permissible Redactions.

a. The parties agree to further meet-and-confer on this subject prior to the commencement of discovery beyond that called for in the Court's Order of July 8, 2021.

10. Production Format for ESI.

a. General Provisions. Except as provided in subparagraphs (b) and (c), below, documents originally collected as electronic files will be converted to *.tif image format with extracted or OCR text and associated metadata set forth on Attachment A ("TIFF-Plus format"). After such production in TIFF-Plus format is complete, a Party may request that particular ESI be reproduced in another format (including native), and the parties will meet-and-confer in good faith as to such requests. If the Receiving Party believes in good faith that a document originally produced in black-and-white should be produced in color, it shall notify the Producing Party, who shall produce a color copy of any such document(s) if it has custody or control of a version of the document in color. If the Producing Party believes that such requests are unduly burdensome, the parties shall meet and confer in good faith to attempt to resolve any

disputes. All references in this Stipulation and Order to TIFF or *.tif images shall apply equally to color JPEG or *.jpeg images produced in accordance with this Stipulation and Order.

b. Spreadsheets, Presentations, Desktop Databases, and Multimedia Files. Spreadsheet files including Microsoft Excel (*.xls, *.xlsx), desktop database files including Microsoft Access (*.mdb or *.accdb), electronic presentations (e.g., PowerPoint), and multimedia files including audio and video will be produced in native format. If any such file requires redaction, the file may be converted to the TIFF-*Plus* format and redacted as needed, or, when appropriate and cost-effective (as agreed upon by the parties after meeting and conferring or as ordered by the Court), a copy of the native file may be redacted (with the text “REDACTED” replacing the redacted content) and the redacted native copy may be produced. Procedures for assigning production numbers and confidentiality information to files produced in native format are addressed in Appendix A, Paragraph A.15.

c. Enterprise Databases. In instances in which discoverable electronically stored information in an enterprise database or database management system (e.g., Oracle, SQL server, DB2) is to be produced, the parties shall meet-and-confer to discuss the most efficient format in which such information should be produced; if such information can be produced in an already existing and reasonably available report, the Parties shall specifically discuss whether production in the reasonably usable TIFF-image form described in Attachment A, is an acceptable report format. If an existing report form is not reasonably available, the Parties shall export from the original database discoverable information in a format compatible with Microsoft Excel or Microsoft Access, and the information shall be produced in that native format.

d. Time Zone. Unless otherwise agreed, all dynamic date and time fields, where such fields are processed to contain a value, and all metadata pertaining to dates and times will be standardized to Universal Coordinated Time (UTC). The Parties understand and acknowledge that such standardization affects only dynamic fields and metadata values and does not affect, among other things, dates and times that are hard-coded text within a file. Dates and times that are hard-coded text within a file (for example, in an email thread, dates and times of earlier messages that were converted to body text when subsequently replied to or forwarded; and in any file type, dates and times that are typed as such by users) will be produced as part of the document text in accordance with subparagraph (a), above.

e. Prior Productions: The parties recognize that a large percentage of the information comprising initial discovery set to commence on August 11, 2021 will constitute information previously produced in the underlying litigation concerning abiraterone acetate between Defendants in this Action and generic manufacturers who are non-parties to this Action (“underlying litigation”). Defendants plan to re-produce that material in this case, in the form it was produced previously (*i.e.*, at no cost to Plaintiffs, with no redactions or withholdings that were not part of the prior productions, with the same Bates numbers that were on the initial production, etc.). The parties agree to further meet-and-confer on this subject prior to the commencement of discovery beyond that called for in the Court’s Order of July 8, 2021.

f. The Parties agree not to degrade the searchability of Documents as part of the Document production process.

11. Additional Procedures for Native Format Files. Any Party seeking to use, in any proceeding in this Action, files produced in native format shall do so subject to the following:

a. If the native file has been converted to TIFF-image or hardcopy, the original production number and confidentiality designation of the native file shall be stamped on each page of the resulting TIFF-image or hardcopy document representing the original native-format file.

b. Use of a file in native format, or use of a TIFF-image or hardcopy document representing the original native-format file shall constitute a representation that the file being used is an accurate and complete depiction of the original native-format file.

12. Production Format for Hard Copy Documents. Documents that exist in hard copy will be produced in accordance with Fed. R. Civ. P. 34. Documents in hard copy that are identified for production, either by the producing Party, or by the requesting Party upon inspection pursuant to Fed. R. Civ. P. 34(a), will be scanned to *.tif image format and produced in accordance with the specifications set forth on Attachment A. Except as set out in section A.12 of the Appendix, the scanning of original hardcopy documents does not otherwise require that the scanned images be treated as ESI.

13. Authenticity and Admissibility. Nothing in this protocol shall be construed to affect the authenticity or admissibility of any document or ESI. All objections to the authenticity or admissibility of any document or ESI are preserved and may be asserted at any time in the litigation prior to any court-imposed deadline. The Parties agree to meet and confer in an attempt to address and/or narrow disputes of authenticity and admissibility in advance of a document's or ESI's use at trial.

14. Confidential Information. Nothing in this Stipulation and Order shall supersede or alter any discovery confidentiality order and/or protective order concerning protection of

confidential or otherwise sensitive information that may be entered by the Court in these proceedings.

15. Reimbursement of Costs. The parties agree to further meet-and-confer on this subject prior to the commencement of discovery beyond that called for in the Court's Order of July 8, 2021.

16. Preservation of Potentially Relevant Information.

- a. Each Party shall be responsible for taking reasonable steps to preserve potentially relevant documents and ESI within its possession, custody, or control.
- b. The following categories of ESI need not be searched:
 - i. Backup data files that are maintained in the normal course of business for purposes of disaster recovery, including (but not limited to) backup tapes, disks, SAN, and other forms of media and that are substantially duplicative of data that are more accessible elsewhere;
 - ii. "deleted," "slack," "fragmented," or "unallocated" data only accessible by forensics;
 - iii. random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system;
 - iv. on-line access data such as (without limitation) temporary internet files, history, cache files, cookies, etc.;
 - v. data in metadata fields frequently updated automatically, such as last-opened or last-printed dates;

- vi SAS program and data files;
- vii Server, system, network, or software application logs;
- viii Data remaining from systems no longer in use that is unintelligible on systems in use;
- ix Electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report;
- x Structural files not material to individual file contents (e.g. .CSS, .XSL, .XML, .DTD, etc.);
- xi Operating System files that do not store user-created content (e.g. CAT, DLL, DMP, EXE, FON, PNF, OPS, SYS, etc.);
- xii Application source code, configuration, and other similar files necessary for the function of an application that do not store user-created content during ordinary use (E.g. BAK, BIN, CFG, DBF, DAT, JS, JSON, JAR, LUA, MSB, RES, WINNT, YTR, etc.) and
- xiii Other forms of ESI, not otherwise addressed in this protocol, whose preservation requires extraordinary affirmative measures that are not utilized in the ordinary course of business.

c. The following categories of ESI need not be searched at this time, but must be preserved in a manner consistent with the Parties' obligations under the Federal Rules of Civil Procedure:

- i. Electronic data (*e.g.*, call logs, email, calendars, contact data, notes, and text messages) stored on mobile devices (*e.g.*, iPhone, iPad, Android, and BlackBerry devices);
- ii. Voicemail .wav files; and
- iii. Text messages and instant messages that are not retained in the ordinary course of business.

17. Definitions. As used in this Stipulation and Order, the following terms shall have the following meanings.

- a. Attachment. An "attachment" is a file (or files) associated with another file (such as an email message) for retention and storage as a single unit.
- b. Document Family. A "document family" is a collection of pages or files produced manually or by a software application, constituting a logical single communication of information, but consisting of more than a single stand-alone record. Specifically as to email, a "document family" is an email and any attachments associated with it.
- c. Electronically Stored Information ("ESI"). "ESI" has the same meaning as in Federal Rule of Civil Procedure 34(a) and Federal Rule of Evidence 1001.
- d. Email Message. An "email message" is a document created or received via any electronic mail system. Any attachments that may be transmitted with an email message, such as word processing and other electronic documents, are not part of the email message, but are part of the Document Family.

e. Load File. A “load file” is a file that provides certain information regarding a set of scanned images or electronically processed files. An image load file indicates, *inter alia*, where individual pages or files belong together as documents, to include attachments, and where each document begins and ends. A data load file typically contains data relevant to the individual documents, such as selected metadata, coded data, and extracted text.

f. Native format. For any item of ESI, “native format” means the file structure defined by the original application in which the file was created.

It is hereby ORDERED:

Edward S. Kiel

Edward S. Kiel, U.S.M.J.

Dated: July18, 2021

WE HEREBY CONSENT TO THE FORM AND SUBSTANCE OF THE FOREGOING ORDER:

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ATTACHMENT A

A.1. Image Files. Files produced in *.tif format will be single page black and white *.tif images at 300 DPI, Group IV compression. Files produced in color will be provided as single page *.jpeg images. To the extent possible, original orientation will be maintained (*i.e.*, portrait-to-portrait and landscape-to-landscape). Each *.tif/*.jpeg image will be assigned a unique name matching the production number of the corresponding page. Such files will be grouped in folders of no more than 1,000 *.tif/*.jpeg files each unless necessary to prevent a file from splitting across folders. Files will not be split across folders and separate folders will not be created for each file. Production (“Bates”) numbers shall be endorsed on the lower right corner of all images. This number shall be a unique, consistently formatted identifier that will:

- a) be consistent across the production;
- b) contain no special characters; and
- c) be numerically sequential within a given file.

Bates numbers should be a combination of an alpha prefix along with a 7- or 8-digit number (e.g. ABC00000001). The number of digits in the numeric portion of the Bates number format should not change in subsequent productions. Confidentiality designations, if any, will be endorsed on the lower left corner of all images and shall not obscure any portion of the original file.

A.2. File Text. Except where ESI contains text that has been redacted under assertion of privilege, other protection from disclosure, or as otherwise provided in this Stipulation and Order, full extracted text will be provided in the format of a single *.txt file for each file (*i.e.*, not one *.txt file per *.tif/*.jpeg image). Where ESI contains text that has been redacted under assertion of privilege, other protection from disclosure, or as otherwise provided in this Stipulation and Order, the redacted *.tif/*.jpeg image will be OCR'd and file-level OCR text will be provided in lieu of extracted text. In other instances where text extraction is not possible, such as with certain *.PDF files, OCR text will be provided. Searchable text will be produced as file-level multi-page UTF-8 text files with the text file named to match the beginning production number of the file. The full path of the text file must be provided in the *.dat data load file.

A.3. Word Processing Files. Word processing files, including without limitation Microsoft Word files (*.doc and *.docx), will be produced in the above format with tracked changes, comments, and hidden text showing.

A.4. Presentation Files. To the extent that presentation files, including without limitation Microsoft PowerPoint files (*.ppt and *.pptx), are produced in *.tif/*.jpeg image format, such *.tif/*.jpeg images will display comments, hidden slides, speakers’ notes, and similar data in such files.

A.5. Spreadsheet or Worksheet Files. To the extent that spreadsheet files, including without limitation Microsoft Excel files (*.xls or *.xlsx), are produced in *.tif/*.jpeg image format, such *.tif/*.jpeg images will display hidden rows, columns, and worksheets, if any, in such files.

A.6. Parent-Child Relationships. Parent-child relationships (*e.g.*, the associations between emails and their attachments) will be preserved. Email and other ESI attachments will be produced as independent files immediately following the parent email or ESI record. Parent-child relationships will be identified in the data load file pursuant to paragraph A.14 below.

A.7. Dynamic Fields. Files containing dynamic fields such as file names, dates, and times will be produced showing the field code (*e.g.*, “[FILENAME]” or “[AUTODATE]”), rather than the values for such fields existing at the time the file is processed.

A.8. English Language. To the extent any data exists in more than one language, the data will be produced in English, if available. If no English version of a file is available, the Producing Party shall not have an obligation to produce an English translation of the data.

A.9. Embedded Objects. Some Microsoft Office and .RTF files may contain embedded objects. Such objects typically are the following file types: Microsoft Excel, Word, PowerPoint, Project, Outlook, and Access; and PDF. Subject to claims of privilege and immunity, as applicable, objects with those identified file types shall be extracted as separate files and shall be produced as attachments to the file in which they were embedded. If the file with the embedded object is produced in native format, the embedded object need not be extracted.

A.10. Compressed Files. Compressed file types (*i.e.*, .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual files.

A.11. Encrypted Files. The Producing Party will take reasonable steps, prior to production, to unencrypt any discoverable electronically stored information that exists in encrypted format (*e.g.*, because password-protected) and that can be reasonably unencrypted.

A.12. Scanned Hardcopy Documents

- a) In scanning hardcopy documents, multiple distinct documents should not be merged into a single record, and single documents should not be split into multiple records (*i.e.*, hard copy documents should be logically unitized).
- b) OCR shall be performed on a document level and provided in document-level *.txt files named to match the production number of the first page of the document to which the OCR text corresponds. OCR text should not be delivered in the data load file or any other delimited text file.
- c) In the case of an organized compilation of separate hardcopy documents—for example, a binder containing several separate documents behind numbered tabs—the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the family fields set out below.

A.13. Production Numbering.

In following the requirements of Paragraph A.1, the Producing Party shall take reasonable steps to ensure that attachments to documents or electronic files are assigned production numbers that directly follow the production numbers on the documents or files to which they were attached. If a production number or set of production numbers is skipped, the skipped number or set of numbers will be noted. In addition, wherever possible, each *.tif image will have its assigned production number electronically “burned” onto the image.

A.14. Data and Image Load Files.

- a) Load Files Required. Unless otherwise agreed, each production will include a data load file in Concordance (*.dat) format and an image load file in Opticon (*.opt) format.
- b) Load File Formats.
 - i. Load file names should contain the volume name of the production media. Additional descriptive information may be provided after the volume name. For example, both ABC001.dat or ABC001_metadata.dat would be acceptable.
 - ii. Unless other delimiters are specified, any fielded data provided in a load file should use Concordance default delimiters. Semicolon (;) should be used as multi-entry separator.
 - iii. Any delimited text file containing fielded data should contain in the first line a list of the fields provided in the order in which they are organized in the file.
- c) Fields to be Included in Data Load File. For all documents or electronic files produced, the following metadata fields for each document or electronic file, if available at the time of collection and processing and unless such metadata fields are protected from disclosure by attorney-client privilege or work-product immunity or otherwise prohibited from disclosure by law or regulation, will be provided in the data load file pursuant to subparagraph (a), above, except to the extent that a document or electronic file has been produced with redactions. The term “Scanned Docs” refers to documents that are in hard copy form at the time of collection and have been scanned into *.tif or *.jpeg images. The term “Email and E-Docs” refers to files that are in electronic form at the time of their collection.

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
PRODBEG [Key Value]	ABC00000001	Yes	Yes	Beginning production number
PRODEND	ABC00000008	Yes	Yes	Ending production number
PRODBEGATT	ABC00000009	Yes	Yes	Beginning production number of parent in a family
PRODENDATT	ABC00001005	Yes	Yes	Ending production number of last page of the last attachment in a family

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
NATIVEFILE	Natives\001\001\ABC0000001.xls	N/A	Yes	Path and file name for native file on production media
FILEDESC	Microsoft Office 2007 Document	N/A	Yes	Description of the type file for the produced record.
FILENAME	Document1.doc	N/A	Yes	Name of original electronic file as collected.
DOCEXT	DOC	N/A	Yes	File extension for email or e-doc
PAGES	2	Yes	Yes	Number of pages in the produced document or electronic file (not applicable to native file productions).
CUSTODIAN	John Beech	Yes	Yes	Custodian who possessed the document or electronic file.
CUSTODIAN_OTHER	Frank Maple; Janice Birch	N/A	Yes	When global de-duplication is used, these are custodians whose file has been de-duplicated; multiple custodians separated by semicolons.
SUBJECT	Changes to Access Database	N/A	Yes	“Subject” field extracted from email message or metadata properties of the document
FROM	John Beech	N/A	Yes	“From” field extracted from email message
TO	Janice Birch	N/A	Yes	“To” field extracted from email message
CC	Frank Maple	N/A	Yes	“Cc” or “carbon copy” field extracted from email message
BCC	John Oakwood	N/A	Yes	“Bcc” or “blind carbon copy” field extracted from email message
AUTHOR	John Oakwood	N/A	Yes	“Author” field extracted from document
DATECREATED	10/10/2005	N/A	Yes	“Created” field extracted from document
DATELASTMOD	10/11/2005	N/A	Yes	“Last modified” field extracted from document
DATESENT	10/10/2005	N/A	Yes	Sent date of email message (mm/dd/yyyy format)
TIMESENT	10:33 am	N/A	Yes	Sent time of email message, time zone set to UTC
DATERCVD	10/10/2005	N/A	Yes	Received date of email message (mm/dd/yyyy format)
TIMERCVD	10:33 am	N/A	Yes	Received time of email message, time zone set to UTC
CONFIDENTIALITY	HIGHLY CONFIDENTIAL	Yes	Yes	Text of confidentiality designation, if any
TEXTPATH	Text\001\001\ABC0000001.txt	Yes	Yes	Path to *.txt file containing extracted or OCR text
PRODVOL	VOL001	Yes	Yes	Name of the Production Volume

A.15. Files Produced in Native Format. Any electronic file produced in native file format shall be given a file name consisting of a unique Bates number and, as applicable, a suitable

confidentiality designation; for example, "ABC00000002_Confidential." For each native file produced, the production will include a *.tif image slipsheet (a) indicating the production number of the native file, (b) with respect to any confidential document, setting forth the confidentiality designation applicable to the native file as provided in the Stipulated Discovery Confidentiality Order, (c) as applicable, indicating that information from the native file has been redacted, and (d) stating "File Provided Natively". To the extent that it is available, the original file text shall be provided in a file-level multi-page UTF-8 text file with a text path provided in the *.dat file; otherwise the text contained on the slipsheet shall be provided in the *.txt file with the text path provided in the *.dat file.

A.16. Production Media. Unless otherwise agreed, documents and ESI will be produced on optical media (CD/DVD), external hard drive, secure FTP site, or similar electronic format. Such media should have an alphanumeric volume name; if a hard drive contains multiple volumes, each volume should be contained in an appropriately named folder at the root of the drive. Volumes should be numbered consecutively (ABC001, ABC002, etc.). Deliverable media should be labeled with the name of this action, the identity of the producing Party, and the following information: Volume name, production range(s), and date of delivery.

A.17. Encryption of Production Media. To maximize the security of information in transit, any media on which documents or electronic files are produced may be encrypted by the producing Party. In such cases, the producing Party shall transmit the encryption key or password to the requesting Party, under separate cover, contemporaneously with sending the encrypted media. The receiving parties in this matter are on notice that certain data produced may originate from custodians in the European Union and the receiving parties therefore agree to follow the strictest security standards in guarding access to said data.